

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

MEMORANDUM OPINION AND ORDER  
(*Daubert* Motion re: Dr. Peter Rosenblatt, M.D.)

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Peter Rosenblatt, M.D. [ECF No. 4833]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **GRANTED in part, DENIED in part**, and **RESERVED in part**.

I. Background

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis.

To this end, I selected certain cases to become part of a “wave” of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

## **II. Legal Standard**

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

### **III. Analysis**

Dr. Rosenblatt is a practicing urogynecologist with extensive experience implanting and removing pelvic mesh devices used in the treatment of SUI and POP.

#### **1. Degradation and Shrinkage**

First, plaintiffs argue that Dr. Rosenblatt’s opinions regarding mesh degradation and shrinkage should be excluded because he is unqualified and his

methodology is unreliable. In particular, they allege that he based his opinions solely on his personal experience, which is either irrelevant to the BSC products at issue or too limited to be reliable. I disagree. An expert may be qualified by “knowledge, skill, experience, training, or education[.]” Fed. R. Evid. 702. “One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion.” *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Here, Dr. Rosenblatt explicitly states that he relied not only on his knowledge and experience, but also on scientific literature, all of which are sufficiently reliable methods of forming his particular opinion. The challenges advanced by the plaintiffs here are more appropriately raised on cross-examination. Therefore, I **FIND** Dr. Rosenblatt’s clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion. Accordingly, the plaintiffs’ Motion is **DENIED** on this point.

## **2. Tissue Integration and Pore Size**

Second, plaintiffs argue that there is no support for Dr. Rosenblatt’s opinion that “there is consistently excellent tissue integration within the mesh [and] the pore sizes allow macrophages to enter within the structure of the mesh during the healing phase so that any bacteria can be dealt with, preventing the infection of the mesh.” Rosenblatt Report 20. BSC does not respond to this argument. Therefore, I **FIND** that Dr. Rosenblatt’s opinion on tissue integration and pore size is unreliable. Accordingly, the opinion is **EXCLUDED**; the plaintiffs’ Motion on this point is **GRANTED**.

### 3. Myofascial Pain

Third, plaintiffs argue that there is no support for Dr. Rosenblatt's opinion that myofascial pain "is another well-recognized cause of post-operative pain after any type of pelvic surgery, . . . whether or not synthetic mesh is utilized in the repair surgery." Rosenblatt Report 22. BSC responds that this opinion is based on Dr. Rosenblatt's clinical experience, as well as the extensive medical literature cited in his report. Further, as BSC points out, plaintiffs did not depose Dr. Rosenblatt regarding his opinions in these cases, which would have given them the opportunity to question him about the support for such opinions. Accordingly, I **FIND** that I do not have sufficient information regarding the support for Dr. Rosenblatt's opinion regarding myofascial pain to make a determination as to its reliability at this time. Therefore, I **RESERVE** ruling on this issue until trial.

### 4. Adequacy of Warnings

Fourth, plaintiffs argue that Dr. Rosenblatt is not qualified to offer expert testimony on the adequacy of the mesh devices' Directions for Use ("DFU") because "[t]here is no evidence in the record that Dr. Rosenblatt has participated in the drafting of a DFU nor served as a consultant on product warnings." BSC responds that Dr. Rosenblatt is qualified because he "has specific experience designing and developing a mesh device for fecal incontinence, including developing the IFU for the device." Indeed, in Dr. Rosenblatt's expert report, he states, "As part of that consulting, I have worked on developing Instructions For Use (IFU) documents to assist surgeons in the proper use of surgical devices and tools. Therefore, I **FIND** that Dr. Rosenblatt possesses additional expertise in the specific area of product warnings

that goes beyond his clinical experience using the products in his own practice. Accordingly, the plaintiffs' Motion on this point is **DENIED**.

#### **5. Material Safety Data Sheet ("MSDS")**

Fifth, plaintiffs seek to prevent Dr. Rosenblatt from testifying about the scientific basis and utility of the language contained in the MSDS for Marlex polypropylene resin. As I have previously held, whether a particular doctor relies on MSDSs in his practice is not helpful to a jury. The pertinent issue is that the MSDS contained a warning allegedly not heeded by BSC, not whether practicing physicians regularly consult the warnings.

BSC argues that Dr. Rosenblatt is qualified to testify on the scientific validity of MSDSs because of his experience in designing and developing a polypropylene mesh device. However, BSC provides no support for this statement, and plaintiffs fail to respond to this argument. As such, I **FIND** that I am without sufficient information at this time to draw the fine line between qualified and unqualified expert testimony on the scientific reliability of MSDSs. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

#### **6. Sterile Environment**

Sixth, plaintiffs seek to exclude Dr. Rosenblatt's opinion that the vagina is a sterile environment, suitable for placement of the mesh. Plaintiffs summarily argue that Dr. Rosenblatt does not provide any support for this opinion. BSC summarily responds that Dr. Rosenblatt's opinion is based on his review of the medical literature, as well as his clinical experience, education, and training. I **FIND** that I am without sufficient information at this time to determine whether Dr. Rosenblatt's

opinion is reliable. Accordingly, I **RESERVE** ruling on until further testimony may be offered and evaluated firsthand at trial.

#### 7. FDA 510(k) Process

Seventh, plaintiffs seek to preclude Dr. Rosenblatt from offering any opinions regarding FDA regulations or approval. Based on this court's prior rulings, BSC does not oppose this argument. Therefore, any opinions relating to the FDA are **EXCLUDED**. The plaintiffs' Motion on this point is **GRANTED**.

#### 8. Position Statements

Finally, plaintiffs seek to exclude Dr. Rosenblatt's references to organizational position statements issued by the American Urogynecologic Society. As I indicated previously during these MDLs, position statements are not expert opinions. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 731–32 (S.D. W. Va. 2014). Dr. Rosenblatt is not using his “scientific, technical, or other specialized knowledge” in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here and **RESERVE** this ruling for trial.

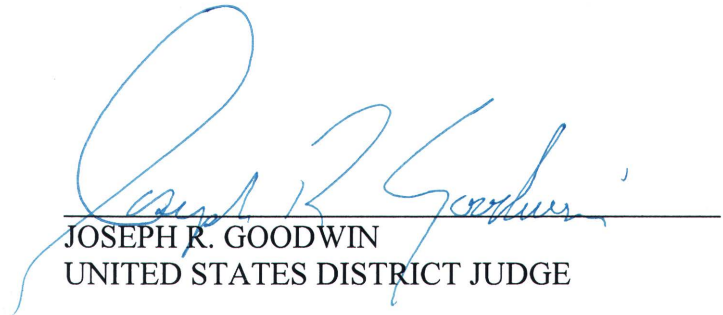
#### IV. Conclusion

To summarize, the plaintiffs' *Daubert* Motion concerning Dr. Rosenblatt [ECF No. 4978] is **GRANTED in part, DENIED in part, and RESERVED in part**.



The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

## **EXHIBIT A – CASE LIST**

<b><u>Plaintiff</u></b>	<b><u>Cause No.</u></b>
Angela Benson	2:17-CV-01996
Ida Adams	2:17-cv-02588
Laceta Blalock	2:17-cv-02446
Carolyn Childress	2:17-cv-02590
Bonnie Cole	2:17-cv-02449
Penny Dickeson	2:17-cv-02592
Debra Gottfreid	2:17-cv-02646
Linda Henjum	2:17-cv-02734
Sandra Mallory	2:17-cv-02459
Dolores Martinez	2:17-cv-02739
Marlene McFolling	2:17-cv-02596
Mary Melrose	2:17-cv-02467
Nancy Reid	2:17-cv-02598
Ellen Rinaldi	2:17-cv-02600
June Clark	2:17-cv-02448
Delores Martin	2:17-cv-02738
Annie Porter	2:17-cv-02470
Angel Pouncy	2:17-cv-02477
Lori Reyes	2:17-cv-02599
Kimberly Allen	2:17-cv-01837
Perla Alvarado	2:17-cv-02243
Christine Babcock	2:17-cv-00701
Sandra Clark	2:17-cv-02110
Linda Dembski	2:17-cv-01074
Amy Harrison-Hood	2:17-cv-02641
Anita Hauff	2:17-cv-01900
Dana Mahnke	2:17-cv-00568
Mary Masterson	2:17-cv-02417
Donna Palmer	2:17-cv-02416
Armentha Price	2:17-cv-01939
Debora Ross	2:17-cv-02107
Margaret Speed	2:17-cv-02244
Amanda Sutliff	2:17-cv-00536
Tammy Tigner	2:17-cv-01241
Zena Hardwick	2:17-cv-01977
<del>Teresa Conners</del>	<del>2:17-cv-01134</del>
Wendei Smith	2:17-cv-01138
Lisa G. Cutlip	2:17-cv-02505
Susan Faso	2:17-cv-01862